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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/753,448	01/04/2001	Susan I. Shelso	06530.0275	3427

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EXAMINER	
PRONE, CHRISTOPHER D	

ART UNIT	PAPER NUMBER
3738	

DATE MAILED: 05/27/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/753,448	SHELSO, SUSAN I.	
	Examiner	Art Unit	
	Christopher D Prone	3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 February 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-44* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-44* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

In response to the applicants inquiry over whether the examiner intended to cite the Fischell's U.S. Patent No. 5,743,874 or Fischell's U.S. Patent No. 5,735,859 in combination with Ravenscroft's U.S. Patent No. 5,702,418 for the rejection over claims 1-4, 7-13, 15, 16, 29, 30, 32-35, and 44, it is believed that the prior examiner intended to use Ravenscroft in view of Fischell (USPN 5,743,874).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-4, 7-13, 15, 16, 29, 30, 32-35 and 44 rejected under 35 U.S.C. 103(a) as being unpatentable over Ravenscroft in view of Fischell (USPN 5,743,874).

With reference to Figure 1, Ravenscroft discloses a delivery system 10 comprising a catheter 11 having self-expanding (10:49) stent 20 disposed on distal end near loading funnel 13. Figure 1 shows that loading funnel 13 is used to compress stent 20 on the distal end of catheter 11 within an outer member 24 during delivery into the patient's body. The catheter 11 further comprises a guidewire 31 and a tubular member 17 comprising at least three radiopaque marker bands 37 that indicate the leading, middle, and trailing ends of stent 20. Figure 5 discloses 4 dark rings indicating four marker bands with the first band being located near the distal end 50 of the stent to

indicate the end that is leading into the vessel and the portion of the stent that will be expanded first. The catheter also has an outer member 24 that is slidable relative to the tubular member (5:15-22) and is configured to retain the stent 20 in a radially compressed position. In one embodiment Ravenscroft discloses an inflatable balloon device 60 disposed on the catheter beneath the stent (7:10-13). The marker bands can be used to indicate a position corresponding to the re-constrain limit of a partially deployed stent (7:53-59). Ravenscroft also discloses the method for implanting a self-expanding stent comprising the following steps; providing the stent/deployment system combination, delivering the system to the target region, partially deploying the stent, re-constraining the stent, and inflating the balloon device to assist the expansion of the stent (6:21-58 and 7:1-41). Ravenscroft discloses the delivery system for a self-expanding stent as claimed. Ravenscroft however fails to disclose that the first marker is located at the distal most leading end of the self-expanding stent.

Fischell teaches an integrated catheter delivery device comprising fluid ports 33, 29, 44, a holding sleeve 20, and a first marker band 80 or 180 at a position corresponding to a distal most leading end of the self-expanding stent 60 to indicate a position of the distal most leading end that serves a "rapid exchange device" thereby reducing the exchanges of parts used to deploy the stent.

Therefore in view of the teachings it would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the delivery system as disclosed by Ravenscroft by including a marker band on the distal most leading end

of the stent as taught by Fischell to create a delivery device with that reduces the procedures required to deploy the stent.

Claims 5, 6 and 17-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ravenscroft as modified by Fischell and further in view of Lenker et al (USPN 5,749,921).

Ravenscroft, as discussed above, discloses the stent delivery device as claimed. Ravenscroft however fails to teach the loading the stent onto the delivery system through the delivery funnel.

Lenker teaches a the device and method of loading a stent 72 into a delivery catheter prior to deployment by attaching removable cartridge 102 comprising flared portion 100 thereby allowing the stent to be loaded in the operating room prior to deployment to avoid shipping and storing the prosthesis in a compressed configuration (7:1-25). After the stent 72 is loaded within sheath 106 it is detached from the delivery system and disposed at the end of a delivery catheter.

Therefore in view of the teachings it would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the delivery device disclosed by Ravenscroft and modified by Fischell in order to incorporate the method of loading the stent as taught by Lenker in order avoid storing the stent in a compressed configuration thereby promoting resilient expansion of the stent to its full diameter when it is released.

Claims 31 and 36-43 are rejected under 35 U.S.C. 103(a) as being unpatentable over St. Germain (USPN 5,534,007) in view of Fischell and Lenker et al (USPN 5,749,921).

St. Germain et al discloses a delivery system 5 for a self-expanding stent comprising a catheter 5 having a tubular member with an inflatable balloon disposed beneath a self-expandable stent 35 and a loading funnel 25 disposed on its distal end. The catheter also includes a holding sleeve 60 and an outer member 40 that is slidable relative to the tubular member (3:26-59). The loading funnel is capable of assisting with compression of the stent by fixing it in place in the axial direction. The tubular member defines a first lumen 15 for guidewire 20 and second lumen for providing a fluid passage (3:57-59). St. Germain discloses the combination of the stent and delivery system as claimed. St. Germain however fails to disclose that the stent is capable of being received within the loading funnel.

Lenker teaches a the device and method of loading a stent 72 into a delivery catheter prior to deployment by attaching removable cartridge 102 comprising flared loading portion 100 thereby allowing the stent to be loaded in the operating room prior to deployment to avoid shipping and storing the prosthesis in a compressed configuration (7:1-25). After the stent 72 is loaded within sheath 106 it is detached from the delivery system and disposed at the end of a delivery catheter.

Therefore in view of the teachings it would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the delivery device disclosed by St. Germain and modified by Fischell in order to incorporate the method of

loading the stent as taught by Lenker in order avoid storing the stent in a compressed configuration thereby promoting resilient expansion of the stent to its full diameter when it is released.

Response to Arguments

Applicant's arguments filed 2/23/05 have been fully considered but they are not persuasive.

Applicant argues that, in regards to the combination of Ravenscroft and Fischell, the asserted motivation and rationale for combining these references is improper and that nothing suggests that the procedures for deploying the stent by the Ravenscroft device will be reduced by including a marker band at a distal most end of the stent. This is not persuasive because according to the applicant's own admittance the need for a step for visualizing a position corresponding to a distal most end of the stent prior to deploying the stent is eliminated though this combination. Therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the delivery system as disclosed by Ravenscroft by including a marker band on the distal most leading end of the stent as taught by Fischell to create a delivery device with that reduces the procedures required to deploy the stent and gives the operator full knowledge of the location of the entire stent.

Applicant also argues that neither St. Germain, the primary reference, or Fischell disclose 3 marker bands, and that the Office Action does not assed otherwise. This is not persuasive because Fischell teaches 3 possible markers. In its embodiments, the Fischell reference discloses two markers (for example, see 80 and 82 in Fig. 1, and 180 and 182 in Fig. 4). Fischell then goes on to teach of a third marker (for example, see 152 in figure 4).

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher D Prone whose telephone number is (571) 272-6085. The examiner can normally be reached on Monday Through Fri 8:30 to 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on (571) 272-4754. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Christopher D Prone
Examiner
Art Unit 3738

CDP

CORRINE McDERMOTT
SUPERVISORY PATENT EXAMINER
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